PLEASE TYPE OR USE BLACK INK

District the state of the state

	Ope UMB statement on revent
ffr Report #	
F/Importer Report #	

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015

10079154-01-00-01	buto	user-facilities, ors and manufacturers	Mfr Report#			-
	AT	ORY reporting	UF/Importer Report #			
FORM FDA 3500g((2/13)	Page 1	of <u>1</u>	546	51.5		FDA Use Onl
A. PATIENT INFORMATION		C. SUSPECT PRODU		HE STATE		DA OSS ON
1. Patient identifier 2. Age at Time 3. Sex (b) (6)	4. Weight	1. Name (Give labeled strengt	3 = 2 = 3			
or Female		#1 Human stool obt	ained from Ope	nBiome		
In confidence of Birth: (b) (6)	90 kgs		ecal microbi	iota)		
B. ADVERSE EVENT OR PRODUCT PROBLEM	THE REAL PROPERTY.	2. Dose, Frequency & Route	Used 3. The	erapy Dates (i m/to (or best e	lf unknown, gi stimate)	ive duration)
1. Adverse Event and/or Product Problem (e.g., defects/mail	functions)	#125 mL via Dobho:		03/06/14		
2. Outcomes Attributed to Adverse Event		#2	gurt 82			
(Check all that apply) Death: Disability or Permanent Da	amane	4. Diagnosis for Use (Indicati	And the	4 7	Abated After	
(mm/dd/yyyy) Life-threatening Congenital Anomaly/Birth		#1 Severe C. diffic	cfle colitis()	11 -	es No	Doesn'
✓ Hospitalization - initial or prolonged Other Serious (Important M		#2	Fi '			Apply Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Device			Exp. Date	Distance .		☐ Apply
3. Date of Event (mm/dd/yyyy) 4. Date of This Report (mm/dd	d/yyyy)	<u>81</u>	1		Reappeared and duction?	After
03/09/2014 03/31/14			2	#1 🗌 Yo	BS No	Doesn't
5. Describe Event or Problem 52 yo man with hepatitis C/cirrhosis admitted on	(b) (6)	9. NDC# or Unique ID		#2 Ye	ps □ No	Doesn't
with pneumococcal bacteremia, successfully treat	ed, but	10. Concomitant Medical Pro	ducts and Therapy Da	-		Apply
then developed severe C. difficile infection whi resistant to treatment with po vancomycin, IV	ch was	Prior to fecal tran	splant was tre	eated with	h po	
metronidazole, and vancomycin enemas. Complicate	d by	vancomycin, IV metr	conidazole, and	vancomy	cin enem	as
ileus, which eventually resolved but continued thigh volume diarrhea. Under fecal transplant via	o have					
nasoduodenal tube (confirmed to be in the 3rd/4t	h d	D. CHICDEST MEDICA	057/105	(Co	ontinue on p	page 3)
portion of the duodenum) on 03/06/14. Diarrhea i on (b) (6) required transfer to ICU for septic	mproved.	D. SUSPECT MEDICA 1. Brand Namo	L DEVICE			
Blood cultures grew 2 strains of pan-susceptible	E.					
coli. Peritoneal fluid also grew E. coli. Treate vasopressors and antibiotics and transferred bac	d with	2. Common Device Name		2b. Pro	ocode	
floor on (b) (b) Remains hospitalized for an u	nrelated	3. Manufacturer Name, City a	nd State			
problem (possible thigh abscess).	- 1					
		4. Model #	Lot #		5. Operator o	of Device
CIÓ		Catalog #	Expiration Date (m	middagad	Health P	rofessional
APR 1 4 2014	1		- Aprilodon Date (m	modyyyy,	Lay Use	r/Patient
APR I 4 2014	1	Serial #	Unique identifier (U	JDI) #	Other:	
	_	6. If Implanted, Give Date (mn	/dd/yyyy) 7. If Ex	planted, Give	Data (mm/de	(Anny)
6. Relevant Tests/Laboratory Data, Including Dates	page 3)				•	
Blood cultures on (b)(6)		8. Is this a Single-use Device Yes No	that was Reprocessed	and Reused	on a Patient	,
Peritoneal fluid culture on (b) (6)		9. If Yes to Item No. 8, Enter N	lame and Address of F	Reprocessor		_
		10. Device Available for Evalu	ation? (Do not send to	FDA)		
		1	Returned to Manufactur	rer on:		
(Continue on	0000 21	11. Concomitant Medical Prod	ucts and Thermov Date		(mm/dd/yyyy	
(Continue on Other Relevant History, Including Preexisting Medical Conditions (e.g., ell race, pregnancy, smoking and alcohol use, hepetic/renal dysfunction, etc.)			, , , , , , , , , , , , , , , , , , ,	1		
Hepatitis C + alcohol induced cirrhosis				<i>(</i> 0-	-Aim	6.
Schizophrenia		E INITIAL REPORTER		(Cor	ntinue on p	26
		4 Name and Address				
,						
				10		

2. Health Professional?

Yes No

Physician

(Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

Initial Reporter Also Sent Report to FDA Yes No Unk.



essional Report

' reporting of ct problems and

Form Approved: OMB No	0910-029	1, Expires:	12/31/201
	See OMB	statement	on reverse

product use errors

The FDA Safety Information and Adverse Event Reporting Program	product use	е етто	rs 1/3	sequence #	5	110	0//
A. PATIENT INFORMATION		1	Dose or Amount	Frequ	ency	Route	
(b) (6) 2. Age at Time of Event or Date of Birth: 64 Years	4. Weight	#1					
In confidence (b) (6)	or kg	#2	41				
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERE	ROR	3. Dat	tes of Use (If unknown best estimate)	, give duration	on) from/to	5. Even	t Abated After Use d or Dose Reduced?
Check all that apply: 1. Adverse Event Product Problem (e.g., defects/malfunction)	ons)		2/21/2014 - 02/2	21/2014		-	res No Doesn't
Product Use Error Problem with Different Manufacturer of	and the second s	#2				#2 🗆	Yes No Doesn't
2. Outcomes Attributed to Adverse Event (Check all that apply)		100000000000000000000000000000000000000	gnosis or Reason for C.Diff Infection	Use (Indica	tion)		Apply t Reappeared After
✓ Death: (b) (6) ☐ Disability or Permanent Di	amage	#2				Reint	roduction? (es No Doesn't
Life-threatening Congenital Anomaly/Birth		0.1-		7 Funtanti	- Deta	#2 D	Apply Tes No Doesn't
☐ Hospitalization - Initial or prolonged ☐ Other Serious (Important M☐ Required Intervention to Prevent Permanent Impairment/Damage	And the second of the second o	6. Lot #1	*	7. Expiration #1	on Date		# or Unique ID
3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mn		#2		#2			0. 0
02/26/2014 04/10/2014			SUSPECT MEDIC	AL DEVI	CE	No.	
5. Describe Event, Problem or Product Use Error on: The patient was initially salvaged in the	ICU from	1. Bra	ind Name				
unresponsive fulminant C.diff with FMT given	by EGD.	_					
She then went to an ECF where her C.diff recu she was started on Vancomycin 125 QID, the ap	propriate	2. Co	mmon Device Name			C	T
dose. She wasn't responding to outpatient ora Vancomycin so a colonoscopy was performed to		0.00		10.		Africa e	
diff as the cause and to rule out other cause diarrhea. Colonoscopy revealed pseudomembrano	s of her	3. Wai	nufacturer Name, City	and State	•	apr 1	4 2014
colitis suggesting recurrent severe C.diff an	d FMT was						
performed. When I was asked about this patien suggested an increase of Vancomycin to 500mg		4. Mo	del#	Lot#			5. Operator of Device
]					Health Professional
		Cat	alog#	Expiration	on Date (mn	vdd/yyyy)	Lay User/Patient
							Other:
6. Relevant Tests/Laboratory Data, Including Dates		Ser	tal #	Other#			
		6. If In	nplanted, Give Date (r	mm/dd/yyyy)	7. If Exp	lanted, G	ive Date (mm/dd/yyyy)
			his a Single-use Devid	ce that was	Reprocesse	d and Re	used on a Patient?
			es to Item No. 8, Enter I	Name and Ad	dress of Re	processor	
7. Other Relevant History, Including Preexisting Medical Conditions	(e.g.,						
allergies, race, pregnancy, smoking and alcohol use, liver/kidney probl 1. Fecal transplant 02/21/2014.	lems, etc.)		TURB (SON)	TERANE N	ENSA	222	270
2. History of hypertension. 3. History of hyperlipidemia.		STATE OF STREET	THER (CONCOM of names and therap)				THE REAL PROPERTY.
4. Chronic low back pain.				, , , , , , ,			'
 Chronic obstructive pulmonary disease. History of pseudomembranous colitis. 							
7. History of septic shock from UTI and C. d 8. History of B12 deficiency.	ifficile.	6 9	EPORTER (See c	onfidentis	dity seeding	an on be	ackl
	The Court of the					7	
C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA)							
Yes No Returned to Manufacturer on:						1	
D. SUSPECT PRODUCT(S)	(YYYY)						
1. Name, Strength, Manufacturer (from product label)			10			6	
Name Fecal Micorbina Mich Biota						1	
Manufacturer:		2. Hea	ith Professional? 3.	Occupation		4.	Also Reported to:
#2 Name:			Yes No Nun				Manufacturer
Strength: Manufacturer:			ou do NOT want your id ne manufacturer, place				User Facility Distributor/Importer

FORM FDA 3500 (1/09)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

546517

B.5. Describe Event or Problem (continued)

... it might assist treatment as it did initially in the ICU. They should have continued her Vancomycin 500mg QID and used the FMT as an adjunctive treatment, not a primary treatment. The treating GI physician however did not continue her Vancomycin after the FMT, thinking that the FMT was enough and it is not. He used the FMT as the primary treatment and that was not the appropriate treatment. After a few days the patient was readmitted with fulminant C.diff colitis. Perhaps she would benefit from emergency surgery immediately, but they waited until morning and the patient died.

Individual Case Safety Report

10079170-01-00-02

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

History of insulin-dependent diabetes mellitus.
History of chronic kidney disease stage III.
Anxiety, depression disorder.

Individual Case Safety Report



ARY reporting of oduct problems and use errors

Page 1 of Z

Form Approved OMB No 0910-0291, Expires: 6/30/2015 See PRA statement on reverse

	FDA USE ONLY
riage unit	549795

Adverse Event Reporting Program

A. PATIENT INFORMATION	2. Dose or Amount	Frequency	Route
1 Patient Identifier 2 Age at Time of Event or 3 Sex 4 Weight	#1 240 ml	once	via colonoscopy
(b) (6) Date of Birth: 23.3 lb			
2 30013 013	#2		
in confidence or 10.6 kg			
B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR	3. Dates of Use (If unknown,	ave duration) from to	To Event Abatad Afrailles
Check all that apply:	(or best estimate)	give duration) from/to	5. Event Abated After Use Stopped or Dose Reduced?
1. Adverse Event Product Problem (e.g., defects/malfunctions)	#1 4/4/2014		#1 Yes No Doesn't
Product Use Error Problem with Different Manufacturer of Same Medicine			Apply
		lles (Indiantion)	#2 Yes No Doesn't
Outcomes Attributed to Adverse Event (Check all that apply)	4. Diagnosis or Reason for #1 Recurrent C. di:		8 Event Reappeared After
Death: Disability or Permanent Damage	I " Recuire. C. C.	rircite	Reintroduction?
(mm/od/yyyy)	#2		#1 Yes No Doesn't
Life-threatening Congenital Anomaly/Birth Defect			Apply
✓ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)		7. Expiration Date	#2 Yes No Doesn't
Required Intervention to Prevent Permanent Impairment/Damage (Devices)	#1	#1	9 NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 4 Date of this Report (mm/dd/yyyy)	#2	#2	
04/11/2014 05/01/2014	E. SUSPECT MEDICA	AL DEVICE	AS IN HIEROS HAVIN AND TO HAVE AN
5. Describe Event, Problem or Product Use Error	1 Brand Name	2.00002	THE RESIDENCE OF LANDS LOSS AND ALL
Patient underwent a fecal microbiota transplant (FMT)			
for a history of recurrent C. difficile on the morning			
of 4/4/2014. His CBC that afternoon showed a	2 Common Device Name		2b. Procode
planelet count of 89,000. (b)(6) later (on (b)(6)) he developed petechiae and was found to have			
a platelet count of 28,000. He required hospital			
admission for platelet transfusion.	3. Manufacturer Name, City	and State	
<u>m</u>			
20 to 10 to	4 Model#	Lot#	5. Operator of Device
		1	Health Professional
Š CTI			
H A	Catalog #	Expiration Date (mm	Add/yyyy) Lay User/Patient
MAY			Other:
6. Relevant Tests/Laboratory Data, including Data	Serial #	Unique Identifier (UI	
Platelet counts:	J Conc. W	Omque identifier (Di	2.7.
(b) (6) : 28,000			
(b) (b) 28,000 MAY 13 2014	6. If Implanted, Give Date (m	m/dd/yyyy) 7. If Exp	lanted, Give Date (mm/dd/yyyy)
WAI TO COL			
	8. Is this a Single-use Device	that was Reprocesse	d and Reused on a Patient?
	Yes No		
	9. If Yes to Item No. 8, Enter No.	ame and Address of Rep	processor
7. Other Relevant History, Including Preexisting Medical Conditions (e.g.,			
allergies, race, pregnancy, smoking and aicohol use, liver/kidney problems, etc.) Inflammatory Bowel Disease			
Recurrent C. difficile	F. OTHER (CONCOMIT	TANT) MEDICAL I	PRODUCTS
(b) (6)	Product names and therapy	dates (exclude treatmen	nt of event)
			1
			*
	G. REPORTER (See co	nfidentiality south	on on backi
	Cooler Jeres 1		ar our eredry
C. PRODUCT AVAILABILITY			
Product Available for Evaluation? (Do not send product to FDA)			
Yes No Returned to Manufacturer on:			
(mm/dd/yyyy)	0		
D. SUSPECT PRODUCT(S)			
1 Name, Strength, Manufacturer (from product label)			
#1 Name: Stool from healthy conor used for FMT			
Strength: Manufacturer:	2. Health Professional? 3. O	crupation	A Alpa Bassadada
			4 Also Reported to:
#2 Name	Yes No Etys:		Manufacturer
Strength: Manufacturer:	5. If you do NOT want your idea		User Facility
	to the manufacturer, place as		☐ Distributor/Importer
FORM FDA 3500 (2/13) Submission of a report does not constitute an addr	section that madical narrannal	the executed entre - 1	and the second section of



UNTARY reporting of nts, product Belems and coduct use errors

Form Approved: OMB No	0. 0910-0291	Expires: 6/30/2015
	See PRA st	atement on reverse

Triage unit	FDA USE ONLY
Triage unit sequence #	364281
Frequen	sev Route

Adverse Event Reporting Program	Page 1	10 × 2				
A. PATIENT INFORMATION			Amount	Frequency	y Route	
1 Patient Identifier 2. Age at Yime of Event or (b) (6) 3. Sex	4. Weight	#1 25 ml		once	naso	gastric tube
In confidence B ADVERSE EVENT, PRODUCT PROBLEM OR E Check all that apply: I. Adverse Event Product Problem (e.g., defects/malfunct Product Use Error Problem with Different Manufacturer	ctions)	3. Dates of U (or best es #1 6/26/14	150	ive duration) fr	Stopp #1	ent Abated After Use sed or Dose Reduced? Yes No Dose Apply Yes No Doses
2. Outcomes Attributed to Adverse Event (Check all that apply) Death: Disability or Permanent (mm/dd/yyyy) Congenital Anomaly/Bil Hospitalization - initial or prolonged Other Serious (Importal Required Intervention to Prevent Permanent Impairment/Damag	nth Defect nt Medical Events) ge (Devices)	#1 Recur: #2 6.100 (b) (or Reason for U rent C. diff (6) 7 # # # # # # # # # # # # # # # # # #	Expiration Da	8. Eve Rel #1	Yes No Doesr Apply ent Reappeared After introduction? Yes No Doesr Apply Yes No Doesr Apply C # or Unique ID
07/31/2014 5. Describe Event, Problem or Product Use Error The patient is a 23 year old man with C-5 q since a MVA in (b)(6) He had multiple recurrences of C. difficile since November' receiving an antibiotic for a UTI. He initiatequired hospitalization for the C. diffici infection. He was treated with several courvancomycin, including a vancomycin taper. S difficile PCR was positive on 5/5/14. Stool 6/2/14 revealed no pathogens on culture, necampylobacter antigen, negative Giardia antigen.	2013 after ally le ses of tool C. studies on gative igen,	Brand Nan Common C	10	nd State	CTU 2014	5. Operator of Device
Cryptosporidium EIA negative, C. difficile is positive. 6. Relevant Tests/Laboratory Data, Including Dates Routine donor testing on 1/13/14, 2/25/14, 6/30/14 were all negative for stool O&P and (b) (4) Moreover, OpenBiome archives at of stool from every donation. The aliquot we and stool O&P and Giardia (b) (4) were both on the stool sample that was used for this	4/24/14 and Giardia n aliquot as pulled negative		d, Give Date <i>(mn</i>	Unique Ident	ifier (UDI) #	Health Professions Lay User/Patient Other: Give Date (mm/dd/yyyy)
Other Relevant History, including Preexisting Medical Condition allergies, race, pregnancy, smoking and elcohol use, liverNidney prest medical history positive for femoral Drosteomyelitis at donor iliac graft site, need bowel and bladder, and GERD.	ns (e.g., oblems, etc.) VT,	9. If Yes to Itel		me and Addres	s of Reprocess	ov Ducts
D. SUSPECT PRODUCT(S) Name, Strength, Manufacturer (from product lebel) Name: Human stool Strength:	/dd/yyyy)	(TER (See con)	(6	6)
Manufacturer: OpenBiome Name: Strength: Manufacturer:		Yes 5. If you do NO	No Physical	cian		4. Also Reported to: Manufacturer User Facility Distributor/Importer

FORM FDA 3500 (2/13)



(CONTINUATION PAGE) OLUNTARY reporting of events and product problems

Page 3 of 3

Adverse Event Reporting Program B.5. Describe Event or Problem (continued)

He underwent fecal transplant on June 26, 2014 using donor stool from OpenBiome (donor (b) (6) Despite the transplant he continued to have diarrhea. Subsequent testing on 7/31/14 revealed that his stool Giardia antigen was positive and stool C. difficile PCR was also positive. He was then treated with a course of metronidazole. Repeat testing on on 8/21/14 showed that the Giardia antigen was now negative, and C. difficile PCR was negative on 8/25/14. I spoke with the patient's mother this morning and she tells me that his diarrhea has resolved. This raises the question as to the source of the Giardia infection and whether the donor stool may have been the source. The patient has no recent travel history and has not drank water from any streams. Water is supplied to his home by a private company (they do not have city water and do not have a well). The patient's mother has discussed this with the local health department. With regards to the donor, screening has been performed every 2 months since January 2014 (see below) and all screening tests have been negative, including stool O&P exams and Giardia (b) (4)

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

Routine donor testing on 1/13/14, 2/25/14, 4/24/14 and 6/30/14 were all negative for stool 06P and Giardia (b)(4) Moreover, OpenBiome archives an aliquot of stool from every donation. The aliquot was pulled and stool 06P and Giardia (b)(4) were both negative on the stool sample that was used for this patient's transplant.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

baclofen, bisacodyl, dantrolene, docusate, famotidine, levalbuterol, loratadine, lorazepam, multivitamin, ondansetron, oxandrolone, oxycodone, promethazine, senna

DS\$ SEP 1 5 2014

Fax: +1 (800) 332-0178

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Form Approved OMB No. 0910-0291, Expires: 6/30/2015 ee OMB statement on reverse.

r use by user-facilities, listributors and manufacturers ANDATORY reporting

Viir Report #	(b) (6)	es One statement of feverse
JF/Importer Re	port#	
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of <u>8</u>	50	503	38	FDA Use Or
C. SUSPECT PRO				
1. Name (Give labeled st	rength & mfr/labele	d		A
#1 OpenBiome 30	mL Fecal Mid	crobiota I	reparation	n
#2				
2. Dosa, Frequency & R	oute Used	3. Therapy	Dates (H unkn	own, give duration
#130mL, Once,	I-Tube	#1 08/0	or best estimate	2)
		-	0/2014	
#2 4. Diagnosis for Use (Inc.)	diantlan)	#2	Event Abates	(4011
#! Refract., sv:				ose Reduced?
			1 Yes	No Doesi
#2 6. Lat#	7. Exp. Date		2 Yes	No. Does
*(b) (6)	#1 02/07	/2014 8	Event Reapp	- Apply
- ' ' ' '	-		Reintroduction	on?
#2 9. NDC# or Unique ID	#2	#	1 Yes	No Does
5. NOCA OF OTHIQUE ID		#	2 Yes	No Does
10. Concomitant Medica	Products and Th	erapy Dates (E	xclude treatme	nt of event)
Chemotherapy for	r lymphoma (5 weeks p	rior); St	ress-dose
glucocorticoids, metronidazole,				
blood pressure			, эстор	
D DIFFERENCE	16A1 55.10		(Continu	re on page 3)
D. SUSPECT MED 1. Brend Name	ICAIL DIEVICE	I NEW Y		
	- Indiana and a second			N.
2. Common Device Nam	•		2b. Procede	
4. Model #	Lot #			erator of Device
Catalog 8	Expiration	Date (mm/dd	שראל	lealth Professiona ay User/Patient
Serial #	Unimus tel	antifar (IIII) à		ther.
Series in	Unique in	entifier (UDI) 8		
6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explan	ted, Give Date	(mm/dd/yyyy)
8. Is this a Single-use De	trice that was Pon	recessed and	Parand an a f	2-1:12
Yes No	wite that was Kep	OCOSSOU EN	Noused on a P	DOO
9. If Yes to Item No. 8, Er	nter Name and Add	dress of Repro	cessor	-P22
			K	SEP 22 2
10. Davice Available for I	Evaluation? (Do no	d send to FDA)		
Yes No	Returned to N	•	r	
11. Concomitent Medical	Products and The	rapy Dates /		dd/yyyy)
The state of the s			Jose acquire	or orem)
				6
E. INITIAL REPORT	TER STATE		(Continu	e on page 3)
	NEN.	THE REAL PROPERTY.		
(k	o)		6	
2. Health Professional?			4. Initial Re	porter Also Sent o FDA
Yes No	Physician		√ Yes	

	FUKINI FUM 330	UM (2113)			Page
	A. PATIENT IN	ORMATION			10 m
	1 Datient Identifier	2. Age at Time	ALL DESIGNATION OF THE PARTY OF	3. Sex	4. Weight
	(b) (b)	of Event: 80	Years	Famala	lb
		Or		Female	Of 10
	In confidence	of Birth:		Male	kg
	B. ADVERSE E	VENT OR PRODU	CT PROBLE	VI	
	1. Adverse Even	t and/or Pro	duct Problem (e	.g., defects/malfi	unctions)
	2. Outcomes Attribut	ted to Adverse Event			
	(Check all that app	(h) (6)	_		
	✓ Death:	(10) (0) _	Disability o	r Permanent Dar	mage
	Life-threatenin		Congenital	Anomaly/Birth D	efect
	Hospitalization	- initial or prolonged	Other Serio	ous (Important M	edical Events
	Required Inter	vention to Prevent Perma	anent Impairment	/Damage (Device	es)
	3. Date of Event (mn			Report (mm/dd	
		1/2014		08/11/2014	
	5. Describe Event or	Problem iple major como	rhidities	(lymphoma	acute
) and severe, o			
		probability of			
	response to Fi events was rep	MT via GJ on ba	ckground of	no adver	se
,	events was rej	Sortea.			
ANT ADVIO		ing respiratory			
4		oniella versus			
ξ		diagnosis of prectrum antibiot.			
ď	empiric antib	iotics initiate	d in the re	ehabilitat:	ion
100		positive and c.			
		DI including tra CT. Patient trea			
5		daxomicin withou			
1	N N N N N N N N N N N N N N N N N N N	IRS with pulmon	ary and GI	sources	
717	implicated.				
1					
חתייים					
3		, *			
1	Continued on page	3			
	contained on page	•		(Continue on	page 3)
		oratory Data, Including			14
	(h)(6)	cool PCR position	e for C. d	descent wi	on th
	pseudomembrano		(b) (6)	doscopy wi	. Cn
			(5) (5)		
			(CTU	
			SEP	2 2 2014	
			. 021	E & SUIT	
				(Continue on	page 3)
	7. Other Relevant Hist	tory, Including Preexist oking and elcohol use, he			
1	1. Lymphoma -	chemotherapy 5	weeks prio	<i>naion, etc.)</i> r includin	a
1	stress dose st		,		
1	2. CHF - sever				
	Recurrent properties of the properties o	neumonias/respi /PEG	ratory fai	lure with	
	president crack				
-					
	Continued on page	3			
1				(Continue on	
5	submission of a re	port does not cons :ility, importer, dist	titute an adm	ilssion that n	nedical
Č	aused or contribu	ted to the event.	andre, main	indeturer of b	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,

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TOAUSEONLY

	469117-01-00-0		Page 2 of 8 5 6 5 0 3 8
10	100111 01:00		H. DEVICE MANUFACTURERS ONLY
1. Check One		Importer Report Number	Type of Reportable Event 2. If Follow-up, What Type?
	Importer		Death Correction
3. User Facility or Importer	Name/Address		Serious Injury Additional Information
			Malfunction Response to FDA Request
			Device Evaluation
			Device Evaluated by Manufacturer? 4. Device Manufacture Date
			Not Returned to Manufacturer (mm/yyyy)
4. Contact Person	5.	Phone Number	Yes Evaluation Summary Attached
6. Date User Facility or	7. Type of Report	8. Date of This Re	No (Attach page to explain why not) or 5. Labeled for Single Use?
Importer Beceme Aware of Event (mm/dd/y		(mm/dd/yyyy)	Yes No
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			6. Event Problem and Evaluation Codes (Refer to coding manual)
0. 4	Follow-up#_		Patient
Age of Device	Event Problem Codes (Re	ter to coding manual)	Code
Patie		u	Device Code
Dev			
Cod			Method
11. Report Sent to FDA?		ere Event Occurred Outpatient	Results
Yes (mm/dd/yyyy)	Hospital Home	Diagnostic Fa	
	— Dalumina M	ome Ambulatory Surgical Fac	Condusions
13. Report Sent to Manufact	Outpatien	Trealment	7. It Remedial Action initiated, Check Type 8. Usage of Device
Yes (mm/dd/yyyy)	Facility		Recall Notification Initial Use of Device
∐ No	Other:	(Specify)	Repair Inspection Reuse
14. Manufacturer Name/Add	ress		Tanan monaring
			Relabeling Modification/ 91 if account reported to PDA under 21 USC 360(f), list correction/ removal reporting number:
			Other.
		*	10. Additional Manufacturer Narrative and / or 11. Corrected Data
G. ALL MANUFACTU	STATE OF THE RESIDENCE OF THE PARTY OF THE P		
1. Contact Office (and Manu	facturing Site for Device		1.1
Name OpenBiome		617-575-2201	
Address		3. Report Source (Check all that a	apply)
/! \ /	4	Foreign	
(b) (4)	☐ Study	
(0)(' /	Literature	
Email Address	3700	☐ Consumer ☐ Health Professi	ional
safety@openbiome.o		User Facility	The rate
 Date Received by Manufacturer (mm/dd/yyyy) 	5.	Company	
09/04/2014	(A)NDA #	Representative	
6. If IND, Give Protocol #	IND#	Distributor	
	BLA#	Other	
7. Type of Report	PMA/ 510(k) #		
(Check all that apply)	Combination _		
5-day 30-day	Product	Yes	SEP 2 2 2014
7-day Periodic	-	Yes	
15-day Follow-up#	OTC Product] Yes	
. Manufacturer Report Num	ber 8. Adverse Event	Term(s)	
		16	
This section annies only	to requirements of the P	aperwork Reduction Act of 1	1995. Department of Health and Human Services OMB Statement: "An agency may not
The same and			AND STREETH ALL ST

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing date sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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conduct or sponsor, and a person is not Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fde.hhs.gov
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(CONTINUATION PAGE)
or use by user-facilities,
distributors, and manufacturers
MANDATORY reporting

Page 3 of 8

age.

FORM	FDA	3500A	(2/13)	(continued,
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Back to Item B.5

Back to Item B.6

Back to Item B.7

Back to Item D.11 Back to Item C.10

PORINI PDA 3300A (Z113) (COMMINGEO)	
	via GJ after 4L PEG and pre-PPI with 8 hour d/c of
flexible sigmoidoscopy conducted to rule out is	d and continued clinical decline. Two days post-FMT chemic and CMV colitis, and evidence of pseudo-membranes
	of diagnosis). Ongoing hypotension and clinical decline. with comfort care measures only, and patient expired.
	cluding respiratory failure and CDI. No objective
adverse events from FMT were noted.	
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)	
P. 7. Other Delevent History, Industry Prescripting Blodies Conditions (e.g. a	flergies, race, pregnancy, smoking and alcohol use, hapalic/renal dysfunction, etc.) (continued)
4. Recurrent CDI	вотуво, таке, ртеупатку, этокту вто вкото озе, первостепа бузитскоп, екс.) (солитова)
- Approximately 6 episodes each following antibi	
 Previous treatments include: Flagyl, Vanco and Vanco suppressive therapy initiated in rehab 	for unclear time period but negative CDI test and thus
discontinued at some point prior to admission	
Concomitant Medical Products and Therapy Dates (Exclude treatment of event)) (For continuation of C.10 and/or D.11; please distinguish)
	DSC
	DSS SEP 2 2 201
	SEP 2 2 201
Other Remarks	

FORM FDA 3500A (2/13)

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use by user-facilities, istributors and manufacturers NDATORY reporting

Page 1 of 25

		e OMB statement on reverse
Mfr Reg	ort# (b) (6)	
	orter Report #	
	56584	O FDA Use Only
CT(S)		
h & mfml	abelerj	
Fecal	Microbiota Prepar	ration

A. PATIENT IN	PORTO				1	000.	10	FDA Use Onl
Committee of the Commit				C. SUSPECT PROD	UCT(S)		THE REAL PROPERTY.	
(b) (6)	2. Age at Time of Event:	3. Sex 4. W	eight	1. Name (Give labeled street	ngth & mfr/labeler	1		
	Or	Female	bs	#1 OpenBiome 30ml			aration	
In comidence	of Birth: (b) (6)	✓ Male	or	#2				
	VENT OR PRODUCT PROP	SLEM	kgs	2. Doss, Frequency & Rou	te Used	3. Therapy Date:	s (If unknown,	give duration)
1. Advorse Evo	_	om (e.g., defects/malfunction	nel	#125mL, Once, NG	Tube	#1 06/26/20		
	uted to Adverse Event	an (e.g., deletes merchelle)	180)	#2	-	#2		
(Check all that app Death:				4. Diagnosis for Use (Indic	etionj		nt Abated Aft	er Usa
	(mmaayyyy)	ility or Permanent Damage		#1 Recurrent C. d	ifficile co	olitis Stop	pped or Dose	Reduced?
Life-threateni		enital Anomaly/Birth Defect		#2		#1 [Yes No	Doesn'i
		Serious (Important Medical	Events)	6 1 m #	7. Exp. Date	#2	Yes No	Doesn't
3. Date of Event (mi	evention to Prevent Permanent Impeir			(b) (6)	#1 12/10/2		nt Reappeare	- Apply
	31/2014	This Report (mm/dd/yyyy)		#2		Rein	troduction?	
5. Describe Event or	Problem	09/19/2014		9. NDC# or Unique ID	#2	#1 🗖	Yes No	Doesn't Apply
23M with C-5	paraplegia and recurrer	it CDI (modified)	Horn	o Noon of Grinder ID		#2 🗍	Yes No	Doesn't
CDI non-respo	Giardia following FMT. nsive to standard there	Briefly, recurren	nt	10. Concomitant Medical Pr	oducts and The	1 –		- Apply
PCR on backgr	ound of negative stool	studies including	~	baclofen, bisacoch	1. dantrol	ene, docusat	e femat	idino
Giardia antig	en, Campylobacter antic	en. Cryptosporidi	1,177	levalbuterol, lora ondansetron, oxano	atadine, la	razepam, mil	tivitami	n
diarrhea, Re-	Underwent FMT via NG b tested (Day 35 post-FMT) and positive for	or	January Charle	itololle, ox	ycodone, pro	methazin	e, senna
Z Stool Glardia	antigen and CDI PCR. T	reated with cours	ا ۵۰			Ć	Continue or	page 3)
CDI negative	ole and repeat testing with subsequent clinical	for both Giardia	and	D. SUSPECT MEDICA	AL DEVICE			
	Ton Dansequene Climica	resolution.		1. Brend Name				
20				2. Common Device Name		2b. f	Proceds	
2				3. Manufacturer Name, City	and State			
		CTU		The state of the state, only	and State			
		SEP 2 2 2014		4. Model 8	Lot#		5. Operator	of Device
		DEL BE COM		Catalog #	Exploation D	ate (mm/dd/yyy)	Health	Professional
						-10 [Lay Us	er/Patient
Continued on page	3			Serial #	Unique Ident	ffier (UDI) #	Other:	
				6. If Implemed, Give Date (m)	n/dd/ssw) [:	7. If Explanted, Giv	Date (2004)	
6. Relevant Tests/Labr	pretory Date, Including Dates	(Continue on page :	3)					
Regular donor	testing on 01/13/2014.	02/25/2014,		8. Is this a Single-use Device	that was Repro-	essed and Reuser	d on a Patien	17
O4/24/2014, and Ova/Parasite and	d 06/30/2014 were all n	egative for stool	1	9. If Yes to from No. 8, Enter I				
collected on 0	4/15/2014, with negative	The sample was		o. ii 100 to Rom No. 6, Enter I	vame end Addre	ss of Reprocessor		
before and after	er collection.	e boreening resur	103					. 1
In addition to	this regular testing r	0.Wimon						1.
Trozen allquot	of every outgoing samo	le to allow	1	10. Device Available for Evalu	atton? (Do not se	and to FDA)		
retrospective i	nvestigations of poten	tially related	- 11	Yes No	Returned to Man	ufacturer on:	(mm/dd/yyy	-
Continued on page		(Continue on page 3)		11. Concomitant Medical Proc	ducts and Therap	y Dates (Exclude I	reatment of e	venti
	ry, Including Preaxisting Medical C	onditions (e.g., eliergies,	71					
11. C-5 quadripi	egia (MVA - (D) (O)	complicated by	- 1-1					
neurogenic blad senna, docusate	der and bowel treated w	with bisacodyl,	1	E INITIAL REPORTER		(Oc	ontinue on p	page 3)
2. Femoral DVT				1 Alama and Add				
3. Osteomyeliti:	s at donor iliac graft	site				10	16	
 GERD Recurrent CD 							- 1	
	rrences (>3), including	1						
hospitalization,	after antibiotics for	UTI						
submission of a repu	ort does not constitute an ad	(Continue on page 3)	,	MANUEL DESCRIPTION				
ersonnel, user facili	ky, importer, distributor, mai	iufacturer or product	2	Health Professional? 3. Oc		4. Ini	tal Reporter	Also Sent

Yes No

Physician

Yes No Unk

PLEASE TYPE OR USE BLACK INK

Sub personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

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Page	2	Of	25

TOA USE ONLY								
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1. Chock One					March Street			facturers o	NLY			
	<u> </u>		JF/Importe	er Report Number	1	Type of Report	able E	vent		2. W Follows	up, What Type?	Person
User Facility		porter			11	Death				Corr	rection	
3. User Fecility or Imp	porter Nem	e/Address			- 1	Serious In	iterv				itional Information	
1					11	Malfunction	-					
							51				ponse to FDA Rec	jues!
										Devi	ce Evaluation	
					3.	Device Evaluat	ed by I	Manufacturer?		4. Device Ma	nufacture Date	
						Not Return	ned to I	Manufactures		(mm/yyyy)		
4. Contact Person			5. Phone	Number	$\dashv 1$	_						
					11	_		ation Summary Atlac				
6. Date User Facility of	f	7. Type of Repor	1	8. Date of This Report	41	☐ No (Attack	nbage	to explain why not) or		5. Labeled fo	or Single Use?	
Importer Became Aware of Event (mm		_	•	(mm/dd/yyyy)	1 1	,				Yes	□ No	
Audie of Every (inti	owyyyy)	Initial			1 _							
	- 1	Follow-up #			6.	Event Problem	and Ev	relustion Codes (Re	er to cod	ling menual)		
9. Approximate	10. Event	Problem Codes (Refer to co	ding manua/I	- 1		ation					
Age of Device	Patient [ode					
	Code	-		-			evice ode	-		7-		
	Device T					u.	30 0					- 1
	Code		·	-		Me	thod	-	-		-	.
11. Report Sent to FDA	?	12. Location W	hore Even	Occurred	1							1
Yes		Hospitel		Outpatient		Res	sults	-	-		-	
No (mm/dd/)	(YYY)	Home		Diagnostic Facility	11		i					- 1
		Nursing	Unes	Ambulatory		Condus	ions			-	-	1
13. Report Sent to Manu	ufacturer?	=	nome Int Treatme	Surgical Facility	7.8	Remedial Actio	on Initi	ated, Check Type	[B. 11s	sage of Device		-
Yes		Facility	nt treatme	nt			,-	_		Initial Use		1.0
No (mm/dd/y	מממ	Other:			11	☐ Recal	Ļ	Notification		_	o. Device	- 1
				(Specify)		Repair	L	Inspection		Reuse		
14. Manufacturer Namel	Address				1 1	Replace	L	Patient Monitoring	2 11	Unknown		
						Relabeling		Modification/ Adjustment	21	USC 360(ff), I	d to FDA under	
						Other:			ror	moval reporter	ng number:	- 1
						U			-			
									_			
O Ann Mamoon					10.	Additional N	lanufa	cturer Narrative	and /	or 11.	Corrected Da	ta
G ALL MANUFAC		A CONTRACTOR OF THE PARTY OF TH								•		
. Contact Office (and M	lanufacturi	ng Site for Device	09)	2. Phone Number								- 1
Name				617-575-2201								- 1
penBiome Address				3. Report Source								
700763				(Check all that apply)	- 1							
/b)	111			Foreign								
(b)	(4)			Study								
	\ /			Literature	1							
Email Address				Consumer								
afety@openbiome	Ora			Health Professional								.]
Data Received by		5.		User Facility	1							-
Manufacturer (mm/dd/y	m	(A)NDA #		Company								
09/04/2014	4	(A)NDA B		Representative	1							- 1
If IND, Give Protocol #		IND#		Distributor	1							
	- 1	BLA#		Other:	1							- 1
		PMA										
Type of Report		510(k)#			1							
(Check all that apply)	1	Combination										1
5-day 30-day	1		Yes									
7-day Periodic	- 1	Pre-1938	Yes		1							
10-day Inital		OTC Product	Yes								DO	
15-day Follow-up			_								SEP 22	5
Menufecturer Report Nu	mbor 8	. Advorse Event	Term(s)								250 00	1
	.]			- 1							SEP ZZ	2014
	- 1			1	1							

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(CONTINUATION PAGE) or use by user-facilities, distributors, and manufacturers MANDATORY reporting

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FORM FDA 3500A (2/13) (continued)

B.5. Describe Event or Problem (continued	1)
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Back to Item

8

Back to Item B.7

Back to Item D.11 Back to Item C.10

Successive donor testing has been pan-negative and safety aliquot used for patient's FMT negative for stool C&P and Giardia (b) (4) Patient had no recent travel/camping history or ingestion of any water from streams. Unclear ir any rehabilitation pool exposures. Patient does have wells but water supplied by private company and local public health department inquiring.

Given safety sample used in actual FMT was negative for O&P and Giardia $^{(b)(4)}$ it seems unlikely the source of the event. The possibility of a false positive Giardia test (with ongoing CDI) or an environmental source exposure is possible given the clinical context.

B.6. Relevant	Tests/Laboratory	Data,	Including	Dates	(continued)	
				-	(occupianos)	

adverse events. Upon learning of the possible AE from (b)(6), OpenBiote pulled the safety aliquot and sent it to a CLIA-certified laboratory for stool O&P and Giardia (b)(4) both of which were

(b) (4) tests for Giardia, (b) (4) and Ova/Parasite were performed on safety aliquot of stool for Donor (b) (6) Specimen (b) (6) Tests were performed on 08/30/2014. Results were as follows: (1) Ova + Parasite Exam: "No ova, cysts, or parasites seen."
(2) Giardia lamblia (b) (4) "Negative"
Please see attached test results for supporting documentation.

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., ellergies, rece, pregnency, smoking and alcohol use, hepatic/renel dysfunction, etc.) (continued)

Concomitant Medical Products and Therapy Dates (Exclude treetment of event) (For continuation of C.10 end/or D.11; placed distinguish)

Other Remarks

CBER

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adverse events, product problems and product use errors

Fern Approved: OMB No. 0816-0881, Expires: 8/30/2016
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Fig. U.S.E. Grav.

	The FDA Sefect Information and		product u	se errore		riago unit	5827	96
	Adverse Event Reporting Program		Page	1 or 2 2	f	0400000	2001	, ,
	A PAID-NI INFORMATION			2. Dego er An	ADURA .	Proguency	Route	
	(b) (6) an isomular 2. Ago of Time or event or	3. 80E	4. Weight	#1 300 mL		Once	9	
	(b) (6) by airei.	- I	97 _{lb}			Onee	Colonese	ору
	years old	✓ Female		02	-7.00			
		☐ Melo	or 44.4 to	02				
	In éeriléanes	-	-				11	
	B ADVERSE TYLKI, PRODUCT PRO	CLLCH MR FRE	SOLE	S. Batmo of Man	(M unimown a	Ivo Guration) from	A Marie A	oved After Man
	Check of that apply:		Section of the Section of	(or best estimated	An)	TO GO GOOD TO TO	Stangard of	Deso Ruducod?
	1. Adverso Event Product Problem (a.g.	ela la reinta a Munerie	ag!	Ø1 07/23/201	4		#1 Yes	
	Preduct Use Since Problem with Differen	o Manualantana	ику	#2	•			Apply
		K MELINGRANAL EL	verso Modicino				02 Yes	No Despire
	2. Overence Andbured to Adverse Event			d. Diagnosis or i	U 100 RECEION	oo (inelootion)	- L	Apply
	= $(D)(D)$			#1 Recurren		rolle	B. Event Ro	copused After
		thy or Permanent O	emage	Infectio	F.		Retained	
	Life-threelening Cones	raise Anomaly Birth	B.4.	9,5			51 Yes	No Doesn's
							-	Apply
	Hospholization - Initial or prelenged Other	Berious (important i	Hedes Evente)	6. Les di		Expiredon Date	02 Tes	Ne Doesn't
	Regulated Intervention to Prevent Permanent In	pelmeni/Demege ((Devices)	81	01		6. NOCO et	Apply
	3. Date of Event (markeyyyy) 4. Date	of this Report (mn	Wall- and	92	15		- 0. 109 00 01	Oregas ID
			MAKERIA					Marine Co.
_1		9/2015		C SURPLU	THE LAKE BY	MEAKER		
	5. Describe Event, Freeham or Product Line Error			1. Brand Name				
	Patient was deemed eligible for	FMT study bas	ed on	Fecal Micz	obiota Tr	ensplant		
	prior hospitalisation and prior a At appointment, patient's overal.	intibiotic fa	Llure.					e near
	reported as "fair." Patient com	nerr-perud	was	2. Common Dovis			25. Pre:	101 m 0000
Z	on 23-Jul-2014 with a son-related	donor Pa-	ceaure	Stool Tran	splant			7
7	completed 24-hour follow-up phone	call on 24-	701-2014					ED 1 0 20m
Ū	Patient was experiencing slight i	atione and a	navered	3. / []	101	161	111	-0 3 W X 11 15
4	negatively for fever, abdominal a	main, nauges.			n	, (b)	141	
TYPE OR USE BLACK INK	vomiting, diarrhea, and loss of a	ppetite. On	31-		101			
m	Jul-2014, patient's daughter comp	leted 1-week	8077010-	4 Madel ()		1.114		
5	up phone call and answered negational pain, hospit	vely on pacie	ont's	4. Medal 0 N/A	- 1	N/A	6, 0	peretor of Device
OZ!	chills, fatigue, loss of appetite	and diarrh	WOIE,	,	1	11/1		Hesth Prefescionsi
9		,		Corden C		Euplradon Dom In	-	
			- 1	W/A	. 1		T LKKKKABANA	Lay User/Petlerit
2					1	N/A		Other:
w	S. Relevant Teatrif. Aboratory Data, Including Data	1		Bariel V		Unique Identifier (
3	N/A		13	N/A	I.	H/A	2011 0	
PLEASE			li	750	1		- 1	
			11	6. If Implement, Gt	VO DOD IMM	HIGHARAN T MP	malamated Alva B	tala (min/dd/yyyy)
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-				8. la tida e Eingle-	t calved care	hat was Remeason	ned had been her	AR A BASIANCE
1			[]	Yes No				South Marrier
				6. If You to Itom No.	. C. Criter Narr	and Addrons of th	ODER ADDAY	
-			11		,	~ 5.10 M 551 D 61 PC	op resuses:	1
1	. Other Relevant History, including Precidening Me ellergies, roce, programar, smaking and elected ver	dical Conditions	0.g.,					
1	Congestive Heart Failure	' neumanek biobis	1.5					
	Atrial Fibrillation		- 11	F. OTHER . 1.4	ANG WHILL	WII . MILLICAL	PR KODNIKE TE	
	Facemokez		11	Product popular on	the women of the	too forelists dead	descriptor to a	
1	Hypertension		11	Vicemin 012 Furcsemide (2	(3/10/201	2 - (h) (6)	1
1	Solgueo		11	Purcoemide (2	1/25/201	4 - (10) (U	
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(. PRODUCT AVAILABILITY	Will be a second of the second	COMPANIES CONTRACTOR	1. Neme and Adde				DOM
	roduct Available for Buduction? (Do not sand proc	and to CBC	The state of the state of		10			
		-		(b)	16		n	
	Yes No Returned to Mentilecturer ex							01
0.0	Safety of the action of the action	(mmody	ועותו		10	/ /		01
	SOUTH OF PERMICING							
	Nome, Obrength, Menufacturer (from product label)							
	News:							
	Strongth:	8						
-	Manufacturer.			2. Hoolin Profession	enal? 3. Ose	ирабо я	4. Aloo	Reperted to:
82	Nema:			Yes No	Physici	an ·		lenule course
1	Strength:		. [[S. If you do NOT we				lear Feelbly
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FE	DRM FDA 3500 (2/13) Submission of a	mont does not	ntibute es ser					TO TO THE PORT OF
	(See See 1818) Annihoration of 8	TOPULL SUGGESTRON CON	INTERNED IN BOMES	alen that medical po	erborinel or th	io bloshed convoct c	er contributed to	the event.

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UATION PAGE

FOR VULUNTARY reporting of adverse events and product problems

Page 3 of 3

MEDWATCH The FDA Seriety Information and Adverse Event Reporting Pregram

B.S. Describe Event of Preblem (confinues)

Patient had experienced formed bowel movements. On 9/15/2014, patient completed a follow-up appointment and noted occasional increased gas. Patient's well-being was reported as "good." Vitals signs were BP (123/64) and pulse (50). Patient was advised to try simethicone (Gas X) for gas/bloating. Between (b) (6)

status. Patient was having dinner and appeared to be 'glazy eyed', therefore, patient was transported to ER department. Neurology was consulted and symptoms were thought to be secondary to complex partial seizures. A CT scan was obtained and patient was started on IV antibiotics and admitted to medicine floor for further evaluation. CT scan did not have any clinically significant changes. Patient was started on Depakote to help with neurological symptoms and discharged. On (b) (6) Infectious Disease was contacted because patient developed a temperature (99.60f) with lethergy and dahydration. Patient was started on IV fluids and instructed to start vancomycin and ceftazidime. Patient continued to develop more connection and began developing trouble swallowing thin and thick liquids. Patient was hospitalized (b) (6) and discharged on (b) (6) Patient passed away on (b) (6) Upon calling to complete 6-month phone call on 20-Jan-2015, research staff was informed that patient had passed away. Based on patient's previous medical history and lack of abdominal/bowel symptoms during post-FMT hospitalizations, it is unlikely that the adverse event is related to study procedure or FMT.

B.S. Relovery Testal Laboratory Dots, Including Dates (continues)

8.7. Other Relevant History, Including Processing Medical Conditions (e.g., elergies, roce, programmy, amolding and electral use, hopeformal dynamical, etc.) (continued)

F. Concentrant Moder Products and Than an Boise forthide treatment of event (continued)

Depakote (10/14/2014 -Torsemide (11/21/2013 -

(b) (6)

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10785375-01-00-01

MEDWATCH adverse even

For VOLUNIARY reporting of adverse events, product problems and product use errors

Form Approved: OME No. 0010-0201, Expired WID/2013 See PRA statement on Mysres.

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MEDWATCH The FDA Salety Information and

FOR VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

Adverse Event Repending Pregram B.S. Describe Event or Problem (continued)

Patient completed a second follow-up appointment on 25-Mar-2014 due to complaints of weakness. Sowel movements were now semi solid and more frequent. Patient developed an infection of the right calf and was placed on topical antibiotics. In addition, caregiver noted that patient had an increased pulse rate and that patient was now in hospice. Patient was noted has having tachycardia and it was recommended that patient was taken to ER; however, caughter declined since patient had hospice status. Patient's daughter was asked to follow-up with PCP for rapid heart rate. Vital signs were BP (123/97) and pulse (157). On (b) (6) patient presented to clinic for wound assessment. Upon arrival to office, patient was not responsive. Patient was evaluated (no pulse was found) and patient was pronounced decessed upon arrival. Sub-investigator began calling subject for 6-month follow-up in June 2014, however, patient's family was unresponsive to research staff calls. Patient was marked as lost to follow-up until January 2015 when research staff checked patient's EMR and noted that patient was deceased.

Based on patient's medical history and concomitant illnesses (right leg infection, left leg ulcer, urinary infections), it is unlikely that the adverse event is related to study procedure or intervention (FMT).

B.A. Relevant Testel-choretory Bats, Including Dense (continued)

B.7. Other Relevant History, including Presideing Medical Conditions (e.g., ellergies, rece, pregnancy, emolding and elcohol use, hepathetenal dystandion, etc.) (continued)

F. Concember Medical Products and Therapy Dotton (Exclude transport of event) (continued)

Metroprolo1 (12/30/2013 (b)(6)

Risperidone (1/7/2014 - (b) (6) Transdol (12/5/2013 - (b) (6)

Cholecalciferol/Vitamin D3 (11/2/2013 - (b) (6)

Ascorbic Acid [10/3/2013] Mirtezapine (9/25/2013 -Omeprazole (9/4/2013 -Collagenase (12/26/201:

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RY reporting of duct problems and use errors

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leason f	or Use (Indication)	#2 Yes No Doesn't
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		#1 Yes No Doesn't Apply
	7. Expiration Date	#2 Yes No Doesn't Apply
	#1	9. NDC # or Unique ID
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Adverse Event Reportin	ig Program										
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See page 2 for comp											
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See page 4 for comp		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-,, -,	E 0	THER (CONC	OMITAR		MCVI E	1200 MIN	276	- Table
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FORM FDA 3500 (1/09)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

The patient has a history of severe pouchitis characterized by abdominal cramping, diarrhea and dehydration. Her longest remission has been 3 weeks. She has recurrent bouts of pouchitis which she ends up in the Emergency Department for hydration and antibiotics. I received information on January 19, 2015 from her physician that she began having a flair and would go on vancomycin. After a few days she felt better, but she usually relapses at 5 days. She went off her antibiotics on January 24. She had a fecal transplant on (b) (6), (b) (4) on January 27, 2015. She noted having continued cramping and diarrhea as before, but the cramps were more intense. A few days later she went to Emergency Department and she was admitted for antibiotics and IV fluids. She was in the hospital 36 hours and is doing better now.

Individual Case Safety Report

DSS REBITION ulcerative colitis total proctocolectomy with β pouch ilocenal anastomosis

582873

Individual Case Safety Report

, report

10788078-01-00-03

DSS FEB 1 1 100 One fecal transplant on January 27, 2015

Individual Case Safety Report

10788078-01-00-04

DSS EB 1 1 2013

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	product use	crrors	dage unit		
The FDA Safety Information and Adverse Event Reporting Program	Page 1	of #	50 X (1010	
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(0)(0)	Male or kg	#2 .	11 11	Colonosco	
\		3. Dates of Use (H unknown, g	tive duration) from/to 15	i. Event Abated After Use	1
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Product Use Error Problem with Different Man	nufacturer of Same Medicine	#2 4. Diagnosis of Reason for U	as (Indication)	12 Yes No Doesn'i	1
2. Outcomes Attributed to Adverse Event		#1 0		3. Event Reappeared After Reintreduction?	7
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Required Intervention to Prevent Permanent Impair		#1 #		i. NDC # or Unique ID	
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C. PRODUCT AVAILABILITY					
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DSS AR - 9 2015

Privanufacturer

User Facility
Distributor/import

FORM FDA 3500 (2/13)

Manufacturer: OPSEN BIOME

Strength:

Strength:

#2 Name:

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Yes No

2 Health Professional? 3. Occupation

6. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

100-20



U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program (CONTINUATION PAGE)

For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

8.5. Describe Event or Problem (continued)

81 go men I oute drawbe in the setting of vocality trested VI situan Preducing C. dell &, who did not report to versearingen po 2- by evens & IV metrorichogs to discensed Fret by colonomy (which about arous passed rembusions within) improved quietly, north per & start Citile, Han Become aboutty, severely it, motor hypotic decidosis, decidosis, decidos

B.6. Relevant Tests/Laboratory Date, Including Dates (continued)

Day of death gluces 33, lotter 3.6, and x-ray neg for perforation

8.7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, prepnancy, smalling and alcohol use, hepatichrenal dysfunction, etc.) (continued)

Bense boulena Jonoran special 0 m 2

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

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Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA distangation reverse.

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2. Does or Amount	Programmy	Road				
250mL stool	Once	Colonoscopy				
412						
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). Detes of Use (If unknown (or best estimate)	n, give duration) fram/to	5. Event Abelied After Use				
d 03/30/2015		#1 Yes No Desert				
2		Apply				
. Dinguistis or Romesn Tor	Use (Indication)	#2 Yes No Decent				
#1 Severe recurren	t C. difficile	8. Event Reappeared After Reintroduction?				
infection #2		#1 TYPE THE TOORSH'T				
		Apply Apply Document				
(b) (6)	7. Expiration Data #1 09/24/2015	Apply				
2	#2	(b) (6) (b)				
E. SUSPĒCĪ MEDIC		(~) (~)				
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N/A						
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Manufacturer Manne, City	and Dicto					
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Model #	Lat#	5. Operator of Device :				
		Health Professional				
Catalog ()	Established Data (mm	/dd/yyyy/ Lay Uper/Patient				
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Cortal C	Chalena Malaritti (110	Other:				
example.	Unique Identifier (UD	m) si				
Marie Control of the Control	1					
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le tinte a Cingle-use Devic	io Brist was Reprocesses	and Reverd on a Patient?				
U Yes U No						
If Yes to flom No. O, Enter N	icino and Addinos of Ros	70000567				
OTHER (CONCOM	ITANTI MEDVICAL I	POBLICTS				
reduct names and therapy	Botos (exclude treatmen	t of event)				
a management						
REPORTER (See or	amildentiality sectio	n on back				
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		THE RESIDENCE OF THE PARTY OF T				

4. Also Reported to:

Manufacturer

User Facility

☐ Distributor/Importer

.... run mining internation and Adverse Event Reporting Program Page 1 (6)162.8 _{tb} ☐ Female 74 kg Wate B. ADVERSE EVENT PRODUCT PROBLEM OR ER Chack all that apply. 1. Advance Breat Product Problem (e.g., defeate/mellinations) Product the Error Problem with Different Manufacturer of Some Medicine 2. Oxiopraes Attributed to Adverse Event (Check all that apply) Desin: Dissibility or Permanent Damage (mm/dd/yyyy) Life-threatening Congenite! Anomaly/Birth Defect Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required Intervention to Prevent Permanent Impalment/Demage (Devices) 3. Date of Event (mm/6d/yyyy) 4. Date of this Report (num/od/nw/) 04/13/2015 06/30/2015 5. Desertine Event, Problem or Product Use Error 86 y/o man with PMHx of Klebsiella pneumonia urinary tract infection (10/2014), ESRD on HD (since \$/2014), DM, CAD s/p CABG, CHF (EF 45%), HTW with recurrent, severe, refractory C. difficile infection following antibiotic treatment for otltis media (9/2014, 10/2014, 1/2015) who had a Fecal Microbiota Transplant perfor (b) (6) $^{30/15}$ with donor stool from Open Biome (Itam (b) (6) unit ID (b) (6) exp 9/24/15). Patient BLACK was doing well initially after transplant with daily formed bowel movement, which was documented on a phone SE TYPE OR USE note on 4/2/15. Approximately 1 week after FMT, patient developed hematuria and was referred to the Emergency Room. 6. Relevant Tester Laboratory Date, Including Dates Stool Culture 4/13/15: Salmonella Group C1 Blood Culture 4/13/14: No growth after 5 days C. difficile 4/13/15, 1/9/15, 10/14/14, 9/12/14: Detected by PCR for Toxin B Gene or EIA for C. difficile toxin A/B Stool Culture 1/9/15 and 1/15/15: No Salmonella, Shigella, Campylobacter or Yersinia Isolated Other Retovant History, Including Precideting Medical Conditions (e.g., allergies, race, pregnancy, ensiting and alcohol use, Iverhidney problems, etc.) 1. Severe, recurrent CDI following antibiotic treatment for otitis media (9/2014, 10/2014, 1/2015). 2. End-Stage Renal Disease on hemodialysis (since 8/2014) 3. Type 2 DM 4. Coronary heart disease (previous CABG) 5. Congestive heart failure (EF 45%) 6. Hypertension C. PRODUCT AVAILABILITY Preduct Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mirsowyyyy) D. SUSPECT PRODUCTISI 1. Menne, Strongth, Elemetecturer (from product lebel) #1 Name: Donor Stool (Item #: (b) (6) Unit ID: (b) (6) Strangth: 250mL Manufacturer. Open Biome 2. Houlth Professional? 3. Occupation

#2 Alame:

Strength:

Manufacturer.

Physician

to the manufacturer, place on "X" in this best:

5. If you do NOT want your Identity electored

Yes No



17210000

Adverse Event Reporting Program

IARY reporting of and product problems

Page 3 of 3

He was similar Profiles (considered)
He was similar Profiles (considered)
He was similar to (b)(6) on (b)(6) days s/p FMT) with sepsis from emphysematous cystitis (urine culture: Klebsiella pneumoniae ssp pneumoniae. Patient was initially treated with ceftriaxone 1g IV daily and had persistently formed bowel movements until treatment with antibiotics. He then developed loose stools secondary to recurrent C. difficile and Salmonella Group C1 without bacteremia. He was treated with a prolonged course of trimethoprim-methoxazole and cephalexin as well as vancomycin 500mg PO g6.

Two months after hospitalization, the patient was evaluated in GI clinic. He completed his antibiotics including vancomycin without any clinical signs of infection. He has formed daily bowel movements without abdominal pain. He had no identifiable risk factors for salmonella infection.

B.S. Relevant Tested abovetory Date, Including Dates (continued)

Urine Culture 4/9/15: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae Urine Culture 10/24/14: >100,000 CFU/mL Klebsiella pneumoniae ssp pneumoniae

CT A/P (b) (6) IMPRESSION: 1. Thickwalled urinary bladder with surrounding inflammatory change. Foci of gas are present within the bladder lumen, and along the bladder wall. While some of the mural foci may be within diverticula, others appear to be intramural. Additionally, two small foci of gas are noted adjacent to the bladder, but completely external to it. At least one of these foci appears to be venous (image 46 of the coronal series), and the other likely also is as well (image 78 series 3). No free fluid around the bladder to suggest frank bladder perforation. Overall findings are consistent with emphysematous cystitis. This was reported to (b) (6) at 7:34 a.m. on (b) (6) 2. Adjacent sigmoid colon is unremarkable, without evidence of inflammation. 3. Bilateral pleural effusions. 4. Nodular liver contour suggestive of parenchymal disease. 5. Abnormal lymph node anterior to the right hip, just lateral to the sartorius muscle, measuring 17 mm, nonspecific. This may be reactive, a metastatic node cannot be excluded.

8.7. Other Relevant Matery, Including Presidency Redical Coastitions (e.g., allergies, race, programoy, emoking and alcohol use, hepaticirenal dystunction, etc.) (continued)

7. Klebsiella pneumonïae urinary tract infection

F. Concomitent Medical Products and Therapy Dates (Exclude treatment of event) (continued)

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(b) (6)

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DL. DO. O. A.	product problems and
The FDA Sefety Information and Adverse Event Reporting Program	TREGO UNI SOQUENCE #
A PATIENT INFORMATION	Page 1 of 3 (60 8168
1. Pertoni isonither 2. Ago at Time of Event or 3. See	2. Dean or Amount
(b) (6) Bato of Birin:	300.1
(b) (6)	
B. ADMINES EVENT. PRODUCT PROBLEM OR ERROR	& kg
and a set apply,	3. Dotos el Usa (Il unknown, give duration) from/to 6. Event Abated After Use 8. Expend or Door Or Doo
1. C Adverse Event Preduct Predict (e.g., Golean/medianations)	THE PARTY OF THE PROPERTY I
Product Use Error Problem with Different Hansfocturer of Same Me 2. Outcomes Apriluted to Adverse Event	
Command and apply)	4. Diagnostic of Ressent for Use (Indicadon) #2 Yes No Desent
Li distallity of Permissan Damago	Be world C doff. B. Event Rappaered After Reintrespecton?
GLife-threatening Congonited Anomely/Binh Dated	P2 P4 P4 P4
Masphalization - Initial or pratenged Other Sedaus (Impariant Medical Ex Required Intervention to Prevent Permanent Imperment/Demage (Devices)	Apply Apply The province of
3. Date of Event (mindelynn) 4. Date of this Report (mindelynn)	81 (D) (G) 81 8-4-2015 B. NBC 0 or Unique ID
6/30/2015 7/2 /-	152
5 Preduct Upo Error	E. SUSPECT MEDICAL DEVICE
Pt with No recurrent c. diff presented to ER	
with 5 day ho dienter /6 lood in stool.	2. Compon Dovico Namo
1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	170 Proceeds
knined Openhame Styl Transplant 6/25/15. Had whenevery (b) (6) should undersite interest	3. Monufesturer Namo, City and State
Had whereapy (D) (O) should audunte internal	A CONTRACTOR OF THE SENS
hemorrhade and mid point descerding when	
area of deep vicention.	4. Model 6 Let p 6. Operator of Device
	Medith Professional
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6. Relovent Tentral aboratory Data, Including Dates CT and parties of the second of t	Cuher:
	Sorial 6 Unique Identifier (UDI) 6
the eigenid wolon. Edwar of inthomersty	6 Wemlanag 61
र्भ व्यक्तिः	6. W Implented, Give Date (mm/dd/yyy) 7. W Explanted, Give Date (mm/dd/yyy)
Poppy images hit charty for cons shor a few	ti. In this a Single-une Covice that was Repressed and Roused on a Patient?
Journe alle	9. If Yes to them No. 8. Enter Hemo and Address of Representer
7. Other Relevant Mistery, including Prescribing Medical Conditions (e.g., adorphis, mes, programmy, ampliant and pleated use the children for the conditions of the condition	The state of the s
7. Gither Rolevant Mistory, Including Presidency Medical Conditions (e.g., acception, new programs, amount and alcohol use, inventidant problems, etc.) CLIFF 4 1/3/5 4 1/30 apr 18-7 (6	F OTHER CONCOURS
The sea This	THE CONCOMITANT MEDICAL PROPULATE
	Product names and thereby down (endude treatment of event)
The LOAD 181.5	1
	G. REPORTER See good from the continue of the
PRODUCT AVAILABILITY	G. REPORTER Sen confidentally section on Dates
reduct Avolichic for Evaluation? (Do not send product to FDA)	Nemo: Address: DSS
Yes No Returned to Manufacturer on:	Modreal:
SUSPECT PRODUCTYS:	Nemo: Addrean: City: Stato: ZIP: UL 81
Name: (D) (6)	Phono 8 State: ZIP:
Cu ungui,	
Manufacturer Open Gio CO (PA): Recal	2. Month Professional? 3. Occupation 4. Also Reperted to:
Strangth:	Tes Like
Monutecturer: PRM FDA 3500 (2/13) Submission of a report flow polyagether.	is it you do not trust your identity discharged User Facility
ATIM POA 3500 (2/13) Submission of a report dean pol executives as a	Distributor/importer

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........ i'ARY reporting of adverse events and product problems

Page 3 of 3

INICHANAICH The FDA Safety information and Adverse Event Reporting Program

with recurrent bloody disables and anemia (6) (6) gancielouir treatment in addition to receiving PRECTRANTUSION (3 units). Was dricharger apen 1. week gancieloris with and rangementation for flo her, on (b) (6), he was readmitted with experie like syndrome. Blood authors were positive har E. odi. CT of abdomen and naturally impassive. Ultrasound of gullballer (b) (6) with medical distriction 3 stones, hall therefroming or perichologythe fluid whether. Whintely takes to or for superstrong and probable wheterny. Postop de: Folonisant withis, descending whom perforation and intra abdominal : supposes. Path was suggests: "late saguela of the underlying direct process. No specific feature are identified to suggest a cause for the ulcerations."

B.O. Robovent Technication con, Including Bonse frontinued Stock of Conference of the Complete to the population of the complete the co vibrio sp, vibrio cholera, yersinia esterolitra, cuterraggiographie E. edi, where pathogenic. E. whi, shes how; guic E whi, shigh. like Fried producing week, Shighla/Entermosia F. cli, eng to sporidium, cyclospone cayetamesis, Entermoba, histolytica, giardia lamblia, advanires F volve. actorires, averina GI/Go; rotorina A & SAPO VINUS.

B.7. Other Relevant Metary, Including Prescripting Cledical Conditions (e.g., elergies, rece, prognancy, smolding and alcohol use, hepoticismal dysfunction, etc.) (continued)

F. Conseminant Medical Products and Thompsy Dates (Enclude transment of event) (continued)

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The FDA Safety Information and Adverse Event Reporting Program



Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse.

.RY reporting of duct problems and use errors
Page 1 of

FDA USE ONLY Triage unit sequence # 1014108

Auverse Lveilt	Reporting Frogram			162	_			1110	10	
A. PATIENT IN	NFORMATION				Dose or Amount		Frequen		oute	
1. Patient Identifier b) (6)	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight	#1	250 cc			5	igmoi	doscopy
	87	✓ Female	lb	#2	250 cc			 -		da
		☐ Male	or kg	"-	250 66			\$	19mo10	doscopy
In confidence	I EVENT, PRODUCT PR	OBLEM OR ES	ROR		ites of Use (# unknow	n, give	duration)			Abated After Use
heck all that apply:					r best estimate)					or Dose Reduced?
. Adverse Even	at Product Problem (e	.g., defects/malfunc	lions)	-	7/02/2015				1 UY	es No Doesr
Product Use E	Error Problem with Differ	ent Manufacturer o	f Same Medicine	11	7/23/2015		//- di di-	. #	2 🗆 Y	es No Doesn
Check all 41-17	uted to Adverse Event				agnosis or Reason for severe, recurr					Reappeared After
Death:	\Box (6) \Box Disa	ability or Permanent	Damage	_	C difficile in	fect	on			es No Doesn
	(mm/dd/yyyy)	genital Anomaly/Bir	th Defect	#2	recurrent C di infection	ffic	le	-	1 0 1	es No Doesn
	a - initial or prolonged \(\sum \) Other	-		6. Lo		7. E	piration I	Date #	2 🔲 Y	es No Doesn
	vention to Prevent Permanent			#1(b) (6)	#1		9	NDC #	f or Unique ID
. Date of Event (m		te of this Report (n		#2		#2				
08/01/2015	*****	/24/2015		E	SUSPECT MEDI	CAL	DEVICE			
	Problem or Product Use Erro			1. Br	and Name					
87 y/o F add	mitted with severe, CDI) which did not r	complicated (difficile weeks of	H						
standard med	dical therapy (IV me	tronidazole/	PO vanco.	2. Cc	ommon Device Mame				2b. 1	Procode
	r 3rd C diff episode with some improvemen								de TI	3
vanco again	afterwards for risi	ng leukocytos	sis and	3. Ma	nufacturer Name, Ci	ty and	State		7.	
diarrhea. Si	he was discharged to ues of weakness, deb	a rehab faci	lity for		•	-		CE	P 1 (D 2015
status decl	ine. FMT repeated a py on 07/23/15 (Open	s outr think	Jby I	II			4	ŞL.	1 4 1	0 2010
sigmoidesco]	py on 07/23/15 (Open	biome (b) (b	declined	4. M	odel#	L	ot#			5. Operator of Device
procedure uncomplicated. Vanco was held. She declined afterward with confusion, pain (unclear where as not										Health Profession
lucid enough	h to indicate), cont	inued diarrhe	a and	C	ntalog #	E	xpiration	Date (mm/d	dmm)	Lay User/Patient
				"					-,,,,,	_
Relevant Tests/	aboratory Data, Including Da	ates		-	rial #		nique Ide	ntifier (UDI)	#	Other:
none				"	rijai w		mqub soc	maner (ODI)	"	
				<u></u>			4	- WE -1		
¥		*	1.	6. H	mplanted, Give Date	(mm/a	מאאאא)	7. If Expla	nted, Gi	ive Date (mm/dd/yyyy)
			The state of the s		this a Single-use Dev	ice th	nt was Re	processed	and Rei	used on a Patient?
			' - 3		Yes No					
				9. #	res to Item No. 3, Ente	r Name	and Addr	oss of Repro	COSSOT	
Other Relevant	listory, Including Preexisting egnancy, smoking and alcohol	Medical Condition	ns (e.g.,							
diabetes, c	ongestive heart fail	ure (diastol:	ic	B	THER (CONCO	MITTA	MEW (JIN	DICAL P	RODU	ICTS
), delerium, anxiety mia, h/o breast cand		lusion,	F. OTHER (GONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event)						
пурстатрация	,,			met	formin, lisinor	oril,	clonaz	epam, f	urosis	mide, ardii,ibuprofen
			11	gab	apentin, insui	, 10	IItazej	orne, o.	Doule	aruri, ibupioren
				0	25222452 42		- Anna m	Obs Con Tolk	or t	whi i
				(5)	REPORTER (See	Goldi	બન <i>તાક</i> (1)	के श्वस्तावा	I ON DE	i i
C. PRODUCT A									6	
Product Available f	for Evaluation? (Do not send	product to FDA)		1		1				
Yes V No	Returned to Manufacture	er on:	/dd/yyyy)							
. SUSPECT P	RODUCT(S)					1			1	
	Manufacturer (from product la									
1 Name: Donor Strength:	Stool (Openbiome (t) (b) -used	7/23/15			1				
Manufacturer: O	penbiome			2. He	alth Professional?	3. Occ	pation		4.	Also Reported to:
		b) (6) -used	7/2/15	E	Yes No	hysici	an .			Manufacturer
Strength:	position				you do NOT want your					User Facility
Man ifacturer: Or	penbiome			to	the manufacturer, place	ce an "	K" in this b	ox:		Distributor/Importe

FORW FDA 3500 (2/13)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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ARY reporting of
ad product problems

The FDA Safety Information and Adverse Event Reporting Program B.5. Describe Event or Problem (continued) abdominal distension. She did not undergo any diagnostic evaluation for this decline. The family decided to pursue hospice, where she died or (b)(6) days post second FMT). B.6. Relevant Tests/Laboratory Data, Including Dates (continued) B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)